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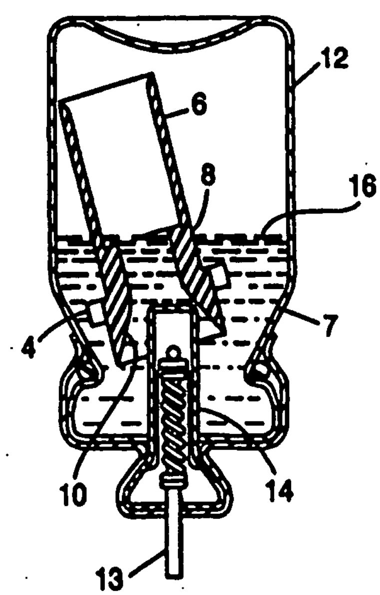
(54) Title: AEROSOL DISPENSER COMPRISING CONTENTS INDICATOR

(57) Abstract

An aerosol dispenser comprising a can (12) equipped with a dispensing valve (14) and containing a pressurized aerosol formulation. The can additionally contains a contents indicator, which, when the aerosol dispenser is shaken, is capable of producing an audible signal which is significantly different when the amount of aerosol formulation in the can is at or below a predetermined level compared to the audible signal when the formulation in the can is above such predetermined level.



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AEROSOL DISPENSER COMPRISING CONTENTS INDICATOR

Field of the Invention

This invention relates to aerosol dispenser devices having means to indicate when the device is approaching empty and in particular to inhalation devices by which medicaments contained in a pressurised aerosol vial are administered to a patient.

Background

Inhalation therapy is becoming an increasingly important method of administering medicaments to a patient. The medicament is formulated with suitable propellant and appropriate other components and charged in an aerosol vial. The aerosol vial is fitted with a valve which generally comprises a metering chamber such that each operation of the valve dispenses a predetermined measured quantity of medicament. The aerosol vial is inserted into an adaptor having a mouthpiece or a port adapted for nasal use and the medicament is administered by firing the aerosol simultaneously with inhalation. Examples of such inhalation devices are the MEDIHALER™ and AUTOHALER™ aerosol inhalation devices commercially available from Minnesota Mining and Manufacturing Company.

With a conventional press-and-breathe device in which the patient fires the device by depressing the aerosol vial whilst inhaling, a rough indication of the amount of medicament remaining in the vial can be obtained by shaking the whole unit. With experience, the user can distinguish the difference in 'feel' between a vial that is substantially full and one that is substantially empty. However, this method is necessarily far from precise and is even less satisfactory with a breath actuated inhaler in which, because of the additional parts, the mass of the aerosol contents is a smaller proportion of the total unit weight.

Alternative methods of assessing the contents of an inhaler aerosol can are to shake it near to the ear to attempt to hear the contents sloshing around, or to float the can in water in order to ascertain the angle it assumes and hence the state of fill. The latter method is clearly only practicable where a bowl, etc., of water is available, and is clearly also cumbersome and time consuming and requires subsequent drying of the can, valve stem etc.

With inhalation devices that utilize an aerosol vial initially charged with a known quantity of medicament, a metered dose of which is dispensed each time the vial is operated, counting the number of operations of the valve will give an indication of the total amount of medicament dispensed and hence the amount of medicament remaining in the vial. Various mechanical counting devices have been proposed which utilize the reciprocating action of the valve stem relative to the can to count the number of operations of the valve. Examples of such counting devices are disclosed in GB 1290484, GB 2191032 and WO 92/09324. However, such mechanical counting devices have not been widely used due to the cost, high degree of accuracy required in manufacturing and/or problems with the reliability of the device.

Thus, there is a need to provide a simple, economical and effective contents indicator which will provide a patient with a warning when the contents of an aerosol can are approaching empty.

Summary of the Invention

According to the present invention there is provided an aerosol dispenser comprising a can equipped with a dispensing valve and containing a pressurised aerosol formulation, the can additionally containing a contents indicator, which, when the aerosol dispenser is shaken, is capable of producing an audible signal which is significantly different when the amount of aerosol formulation in the can is at or

below a predetermined level compared to the audible signal when the formulation in the can is above said predetermined level.

The invention provides a cheap, simple and robust construction which allows the patient to clearly differentiate between a can having a predetermined level of contents, i.e., approaching empty, and one containing a slightly greater volume of liquid, simply by gently shaking the can. The "predetermined level" need not represent a precise volume remaining in the can and it is sufficient to provide a general warning that the contents are low. The contents can be used either in press-and-breathe or in breath-activated inhalation devices, such as Autohaler. The invention provides a genuine 'contents left' indicator, which cannot be interfered with by the patient and may be function tested during manufacture. Furthermore, the contents indicator may assist agitation of the can contents prior to use, but does not require activation of the inhaler in order to assess the can contents.

The contents indicator of the invention may be constructed to provide a significantly louder audible signal when the aerosol formulation in the can is at or below a predetermined level. An example of such an arrangement is a "captured" rattle which cannot impinge on the sides of the can or valve until the amount of formulation in the can is reduced to a predetermined level and thereafter the rattle is "released" and will impinge on the sides of the can or valve to make a distinctive audible signal.

Alternatively the contents indicator may be constructed to provided a significantly quieter audible signal, e.g., substantially silent, when the formulation is at or below the predetermined level. An example of such an arrangement is a free rattle which impinges on the sides of the can or valve to make a distinctive sound and which is captured when the aerosol formulation in the can is reduced to a predetermined level to prevent the rattle impinging on the sides of the can or valve, i.e., the rattle becomes distinctly quieter.

In general, the contents indicator is constructed and arranged such that the aerosol dispenser should be held with the valve extending downwardly and shaken in the horizontal plane to assess the contents since this is the normal orientation of the aerosol dispenser for use. However, the contents indicator may be configured to operate in other orientations of the aerosol dispenser.

Whilst it is known that the mixing of the contents of an aerosol can when it is shaken may be aided by the addition of a ball bearing to the product in the can it will be appreciated that the sound produced when shaking such a can changes gradually and probably insignificantly as the contents of the can are used up. There is no predetermined or threshold level of contents at which there is a significant change in the sound and thus such an arrangement is not an effective contents indicator.

Brief Description of the Drawings

The invention will now be described with reference to the accompanying drawings in which:

Figure 1 represents a cross-section through a rattle suitable for use in the invention;

Figure 2 represents a perspective view of the rattle of Figure 1;

Figure 3 represents a cross-section through a preferred embodiment of a rattle for use in the indicator;

Figure 4 represents a cross-section through an aerosol dispenser incorporating the rattle of Figure 3, with the level of the contents above the threshold level;

Figure 5 represents a cross-section as in Figure 4, but with the level of the contents below the threshold level;

Figures 6 to 9 represent cross-sections through aerosol dispensers having different rattles in accordance with the invention.

Detailed Description

In the Figures, like numerals indicate like features.

The rattle shown in Figures 1 and 2 comprises a cylindrical element (2) and a circumferential flange (4), which is preferably castellated. In the case of a typical metered dose aerosol, the rattle should preferably have an outer diameter less than 16mm in order to allow it to be passed through the neck of the aerosol can during assembly. The rattle may be constructed of metal or rigid plastics material.

Figure 3 illustrates a preferred embodiment of a rattle, similar to that shown in figures 1 and 2. The rattle comprises an upper cylindrical section (6) and a lower cylindrical section (8), the upper section having a larger inner bore than the lower section to reduce the mass of the upper section allowing the rattle to float higher in the can, compared to the rattle of Figures 1 and 2. The upper section (6) may be thinned further or be castellated, etc., to reduce further its mass relative to that of the lower section (8). The rattle should float high enough in the can contents to allow the threshold level to be as close to exhaustion of the can contents as is required.

Figures 4 and 5 show the rattle of Figure 3 positioned within an aerosol can (12) which is equipped with a valve (13). In Figure 4, the level of the contents (16) is above the predetermined or threshold level. The floating rattle is able to move laterally by a few millimetres to strike the inside of the can walls when the aerosol is gently shaken horizontally producing a loud distinctive sound.

Depending upon the particular dimensions of the rattle, the level of contents and degree of shaking one or more of the upper cylindrical section (6), circumferential flange (4) and lower sections (8) will contact the internal wall of the aerosol can (12).

As the contents are used the level reduces until eventually at the threshold level (16a) the rattle straddles the valve as shown in

Figure 5. The clearance between the walls of the bore (9) of the rattle and the side (14) of the valve (13), typically of around 0.15mm, is such that the rattle cannot contact the internal wall of the can (12). Because the rattle cannot move very far laterally, it is unable to strike the valve with enough force to produce much audible signal. Thus, the volume of the audible signal produced when the can is shaken is greatly reduced thereby providing an indication that the can is approaching empty.

The rattle shown in Figures 3, 4 and 5 is longer in the axial direction than that in Figures 1 and 2 to keep it at a suitable angle to facilitate straddling the valve and to prevent the rattle from turning over in the can. The large diameter circumferential flange (4) also helps to guide the rattle over the valve as the flange contacts the walls of the tapering shoulder region (7) of the aerosol can.

The precise position of the circumferential flange may be adjusted for different valve and aerosol can combinations. The castellated or serrated outer edge of this flange prevents it sticking to the inside wall of the can since it decreases the surface area in contact with the wall. The central bore of the rattle may be ribbed to decrease the surface area contacting the valve, and to save plastic. The castellations of the flange may also increase the loudness of the rattling sound generated. The flared mouth (10) assists in guiding the rattle over the valve. In the case of a 50mcl 3M Loughborough metered-dose aerosol valve with a diameter of 5.6mm, the inner bore of the lower portion of the rattle in Figure 3 should be 5.9mm, providing a close fit to the valve. The position of the close-fitting inner bore section may be chosen to be further up or further down the rattle, in order to alter the threshold level at which the loudness of the audible signal is reduced.

Preferably this rattle component is injection moulded from a fairly hard thermoplastic which floats in the can contents. In one

preferred embodiment polyamide ('Nylon') is used, as this acts as a desiccant to remove unwanted water from the formulation and is already approved for this use by regulatory authorities for a number of formulations. The floating rattle could take the place of the nylon desiccant insert used in some products.

In Figures 6 to 9 the position of the rattle below the threshold level is shown in dotted outline.

The embodiment shown in Figure 6 is an example of a free rattle which is captured when the contents of the can fall to a predetermined level.

The indicator comprises a floating rubber cage (18) and a ball bearing (20).

When the contents (16) are above a threshold level as shown at (16a) there is no contact between the cage (18) and ball bearing (20) and shaking of the can (12) allows the ball bearing to hit the inner wall of the can (12) producing a distinctive audible sound.

As the level of contents is reduced to below the threshold level (16a in dotted outline) the floating rubber cage captures the ball bearing (20) as shown in dotted outline preventing it from hitting the interior wall of the can and silencing or substantially reducing the sound of the rattle.

A further embodiment is shown in Figure 7 in which the indicator comprises a floating, rubber dumb-bell shaped component (24) and a metal striker in the form of a washer (26).

The sizes of the rubber and metal components are chosen to ensure that they cannot wedge down the sides of the valve, and to ensure that they float in the formulation.

When the contents of the can are above the threshold level (16), only the rubber component is able to contact the internal wall of the can (12) and the side (14) of the valve, as shown in Figure 7. However, when the level of contents has reduced to the threshold level

(16a) the metal washer is able to contact the valve (as shown in dotted outline), producing a significantly louder and distinctive metallic sound when the can is shaken horizontally compared with the subdued sound produced solely by the rubber dumb-bell striking the can when the contents are above the threshold level.

Figure 8 illustrates an indicator comprising a rubber cage (28) and a floating rattle (30) which is preferably of Nylon. When the contents (16) of the can are above the threshold level (16a), and the can (12) is shaken horizontally in the orientation shown, with the valve lowermost, the floating rattle (30) is only able to strike the rubber cage, which makes little sound. When the contents are reduced to the threshold level (16a), the rattle (30) shown in dotted outline is able to contact the wall (14) of the valve (13) producing a significantly louder and distinctive audible signal.

A further embodiment shown in Figure 9 which comprises a buoyant member e.g. a nylon float (32) and a non-buoyant member e.g. a ball bearing (34) enclosed in a thin plastic or rubber cage (36). Above the threshold level (16) the nylon ball floats and is not able to contact the ball bearing when the can (12) is shaken horizontally. When the liquid level is reduced to the threshold level (16a) the cage tips over as shown in dotted outline (32a and 36a) and the two balls are free to rattle together when the can is shaken horizontally producing a distinctive sound.

CLAIMS:

1. An aerosol dispenser comprising a can equipped with a dispensing valve and containing a pressurised aerosol formulation, the can additionally containing a contents indicator, which, when the aerosol dispenser is shaken, is capable of producing an audible signal which is significantly different when the amount of aerosol formulation in the can is at or below a predetermined level compared to the audible signal when the formulation in the can is above said predetermined level.

2. An aerosol dispenser as claimed in Claim 1 in which the contents indicator produces an audible signal when the aerosol dispenser is shaken which is significantly quieter when the aerosol formulation in the can is at or below said predetermined level than when the aerosol formulation is above said predetermined level.

3. An aerosol as claimed in Claim 1 in which the contents indicator produces an audible signal when the aerosol dispenser is shaken which is significantly louder when the aerosol formulation in the can is at or below said predetermined level than when the aerosol formulation is above said predetermined level.

4. An aerosol dispenser as claimed in Claim 2 in which the contents indicator comprises a buoyant element, which is dimensioned to straddle the valve to limit movement of the buoyant element thereof when the aerosol formulation in the can is at or below said predetermined level.

5. An aerosol dispenser as claimed in Claim 4 in which the buoyant element additionally comprises a circumferential flange for striking the wall of the can.

6. An aerosol dispenser as claimed in Claim 5 in which said circumferential flange is castellated or serrated.

7. An aerosol dispenser as claimed in Claim 4 in which the buoyant element is of sufficient length to prevent it turning over in the can thereby maintaining a suitable orientation to straddle the value.

8. An aerosol dispenser as claimed in Claim 4 in which the buoyant element is formed of polyamide.

9. An aerosol dispenser as claimed in Claim 2 in which the contents indicator comprises a rattle which is free to impinge on the inside of the can when the aerosol formulation is above said predetermined level and a capturing component which restricts movement of the rattle to prevent impingement of the rattle on the inside of the can when the aerosol formulation is at or below said predetermined level.

10. An aerosol dispenser as claimed in Claim 9 in which the rattle comprises a metal ball and the capturing component comprises a buoyant cage.

11. An aerosol dispenser as claimed in Claim 3 in which the contents indicator comprises a buoyant rattle formed of two or more materials, one material being free to contact the can and/or valve when the aerosol formulation in the can is above said predetermined level and a different material being free to contact the can and/or valve only when the contents are at or below said predetermined level to produce a significantly different sound.

12. An aerosol dispenser as claimed in Claim 11 in which the rattle comprises a rubber component in the shape of a dumb-bell and a metal component, in the form of a washer fitted around the centre of the dumb-bell.

13. An aerosol dispenser as claimed in Claim 11 in which the rattle comprises a buoyant mass having a metal component extending downwardly therefrom when the buoyant mass is floating on the aerosol formulation.

14. An aerosol dispenser as claimed in Claim 3 in which the contents indicator comprises a fixed, porous cage and a buoyant component within the cage such that when the amount of aerosol formulation is above said predetermined level the buoyant component is able to impinge only on the cage and when the amount of aerosol formulation is at or below said predetermined level the buoyant component is able to impinge against a different surface generating a significantly different audible signal.

15. An aerosol dispenser as claimed in Claim 14 in which said different surface is the wall of the can or valve.

16. An aerosol dispenser as claimed in Claim 14 in which said different surface is provided by a second, non-buoyant component within the cage.

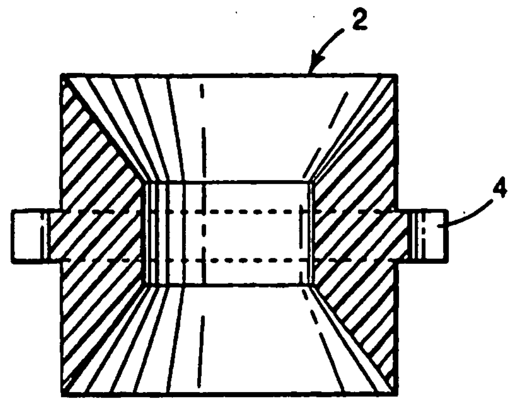

FIG. 1

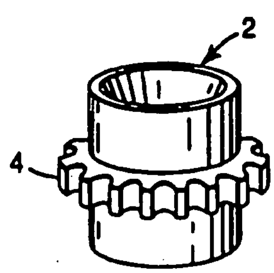

FIG. 2

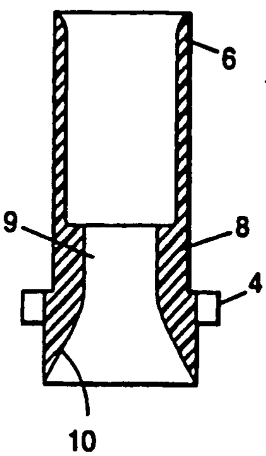

FIG. 3

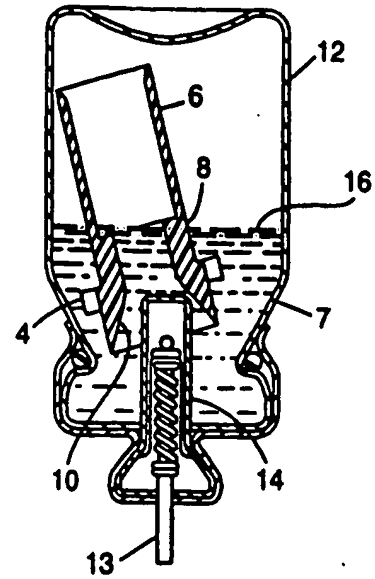

FIG. 4

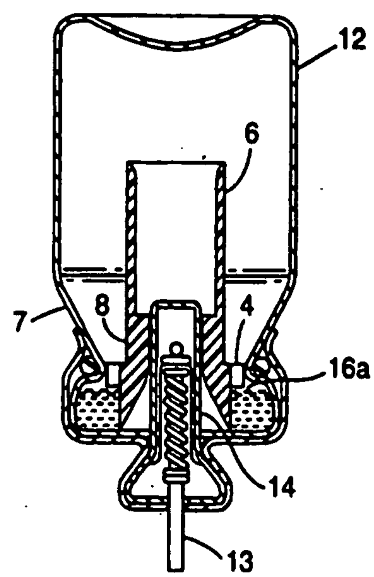

FIG. 5

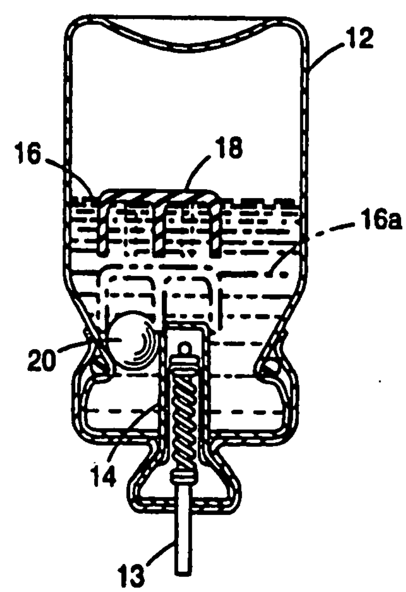

FIG. 6

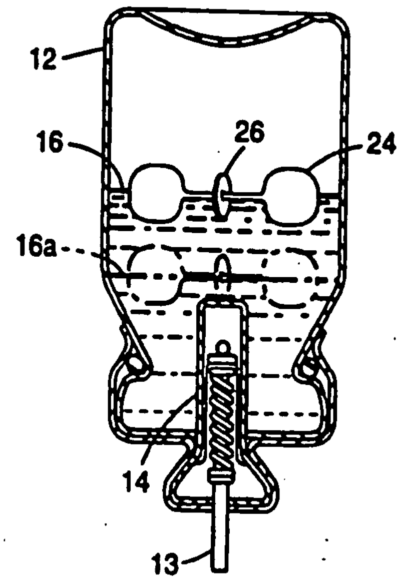

FIG. 7

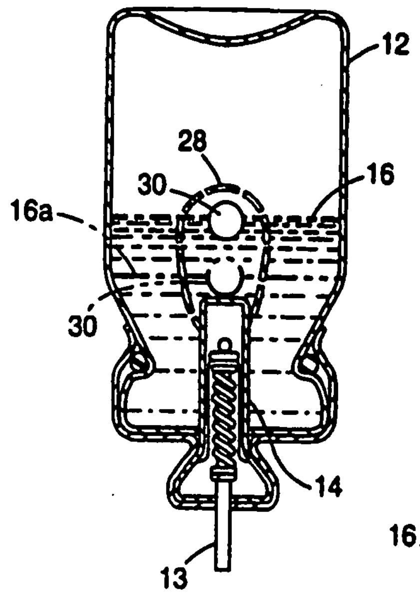

FIG. 8

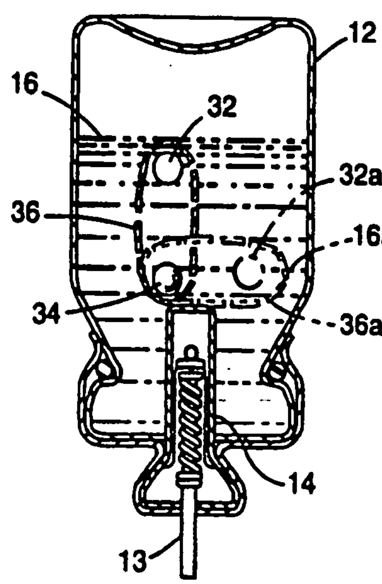

FIG. 9

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 95/10738

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 B65D83/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Date of the actual completion of the international search

12 December 1995

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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